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AF / 1654



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**RESPONSE UNDER 37 C.F.R. § 1.116  
EXPEDITED PROCEDURE REQUESTED  
EXAMINING GROUP 1654**

**PATENT**

Customer No. 22,852

Attorney Docket No.: 06478.1462-00

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of:	)	
Jürgen RÖMISCH et al.	)	Group Art Unit: 1654
Serial No.: 10/033,777	)	Examiner: Michael V. Meller
Filed: January 3, 2002	)	
For: STABILIZED LIQUID PREPARATION	)	<b>Box AF</b>
OF THE PROTEASE WHICH	)	
ACTIVATES BLOOD COAGULATION	)	
FACTOR VII, OR OF ITS PROENZYME	)	

**RECEIVED**

SEP 10 2003

TECH CENTER 1654/2003

Commissioner for Patents and Trademarks  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

**AMENDMENT AND RESPONSE UNDER 37 C.F.R. § 1.116**

In reply to the final Office Action dated June 26, 2003, Applicants submit the following remarks.

**REMARKS**

Claims 1-24 are currently pending in this application.

Applicants thank the Examiner for the telephonic interview of February 25, 2003, and wishes to assure the Examiner that the intent of the undersigned was not to infer that the Office Action was a mistake or to accuse the Examiner of an inappropriate Office Action. Rather, the undersigned called to obtain clarification of the Sato et al.

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reference and obviously was not artful in his request. He sincerely regrets this misunderstanding.

Finally, although not expressly stated in the present Office Action, Applicants note that the rejection of the pending claims as being indefinite under 35 U.S.C. § 112, second paragraph, as anticipated under § 102(b) over Sato et al. or Suganuma et al. and as obvious under § 103 over Sato et al. or Suganuma et al. in view of Pader, Ritchey et al. and Hoppe et al. have not been maintained, and therefore, are presumed to be withdrawn.

#### **Finality of the Rejection**

The pending Office Action was made final on the basis that "Applicant's amendment necessitated the new ground(s) of rejection presented in this Office Action." See Office Action at p. 3. Applicants respectfully request the finality of the rejections be withdrawn.

According to section 706.07(a) of the M.P.E.P., "[u]nder present practice, second or subsequent actions on the merits shall be final, *except where the examiner introduces a new ground of rejection that is neither necessitated by applicant's amendment of the claims . . . .*" M.P.E.P. § 706.07(a) (emphasis added). Here, Applicants' amendments did not necessitate the new grounds for rejection, as the amendments to claim 1 did not add or cancel claimed subject matter nor did the amendments change the scope of the pending claims. The amendments to claim 1 were made to clarify the scope of the claimed invention in response to the Office's statement that "[c]laim 1 is confusing since it is not clear how a pH range can be

considered to be a separate ingredient in the composition." See January 14, 2003, Office Action at p. 5. Despite being amended to make clear that it is the claimed preparation that has a pH from 2.0 to 8.0, claim 1 encompasses the same subject matter. See M.P.E.P. § 706.07 ("Switching . . . from one set of references to another by the examiner in rejecting in successive actions claims of substantially the same subject matter, will alike tend to defeat attaining the goal of reaching a clearly defined issue for early termination . . . .")

Because claim 1, as amended, encompasses the same subject matter as unamended claim 1, Applicants believe that making the rejection final is premature and respectfully request the finality of the rejection be withdrawn.

**Rejections under 35 U.S.C. § 103(a)**

The Office has newly rejected claims 1-21 under 35 U.S.C. § 103(a) as being unpatentable over JP 2000023696 or EP 952215 taken with Sato et al. and further in view of Roy et al. or Kessler et al. See Office Action at p. 3. Applicants respectfully traverse this rejection as the Office has failed to establish a *prima facie* case of obviousness.

As set forth in section 706.02(j) of the M.P.E.P., an Office Action wherein the claims are rejected under 35 U.S.C. § 103 should set forth:

- (A) the relevant teachings of the prior art relied upon, preferably with reference to the relevant column or page number(s) and line number(s) where appropriate,
- (B) the difference or differences in the claim over the applied reference(s),

(C) the proposed modification of the applied reference(s) necessary to arrive at the claimed subject matter, and

(D) an explanation why one of ordinary skill in the art at the time of the invention was made would have been motivated to make the proposed modification.

Here, the Office has cited five references, four of which are newly cited, without setting forth the relevant teachings of the prior art with reference to either column number or page number, the differences between the claimed invention and the applied references, the proposed modification of the applied references necessary to arrive at the claimed invention, or why one of skill in the art would be motivated to modify the references to arrive at the claimed invention. See M.P.E.P. § 706.02(j). Applicants are therefore uncertain as to how the Office is applying each of the references to support the obviousness rejection.

The only basis given for the Office's rejection is that "[i]t is well known that it is *prima facie* obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose." See Office Action at p. 3. The Office continues by stating "since the individual ingredients are known in the art to be used individually for the same purpose, to use them together is obvious." *Id.* The Office, however, has not informed the Applicants as to what ingredients are taught by the applied references or how those ingredients are apparently used for the same purpose as the claimed invention. For this reason, the Office has failed to establish a *prima facie* case of obviousness.

Additionally, Applicants contend that the Office has failed to meet the three criteria necessary to establish a *prima facie* case of obviousness. A *prima facie* case of obviousness is met only if: (1) all claim limitations are taught or suggested, (2) there is some suggestion or motivation to modify the references or combine reference teachings, and (3) there is a reasonable expectation of success. M.P.E.P. § 2143.03.

Applicants respectfully submit that the references provided by the Office do not teach or suggest all claim limitations. JP 2000023696 and EP 952215 disclose a protease or proenzyme capable of activating blood coagulation factor VII. These primary references, however, fail to teach or suggest all of the claimed elements. Particularly, the references fail to disclose at least any of the compounds recited in part (b) of claim 1 or the addition of an ionic or nonionic detergent as recited in dependent claims 2 and 3.

It is not clear how Sato et al. or the new secondary references, Roy et al. or Kessler et al., cure these defects. None of these references teach or suggest a protease or proenzyme capable of activating blood coagulation factor VII as claimed. Further, none of the references teach or suggest the use of any their disclosed subject matter with a protease or proenzyme that activates factor VII in order to arrive at the same subject matter claimed in the instant application.

While the Office has previously relied on Sato et al. to disclose tranexamic acid, Applicants note again that the reference does not teach or suggest the use of tranexamic acid with a protease or proenzyme capable of activating blood coagulation factor VII. Further, Sato et al. states that tranexamic acid is used in oral compositions,

such as dentifrices because it is effective for *periodontosis propylaxis* (sic prophylaxis). See Sato et al., column 1, lines 8-13. Tranexamic acid is not used in Applicants' claimed invention as a prophylactic for periodontosis but rather, as a stabilizer, a use not disclosed or suggested by Sato et al. See Specification, p. 2, lines 12-22. Therefore, tranexamic acid is not known in the art to be used individually for the same purpose as the claimed invention and, accordingly, it is not obvious to combine it with the claimed protease or proenzyme. See M.P.E.P. § 2144.06.

As to the secondary references, Roy et al. and Kessler et al., the Office has not indicated on what portions of these references it relies. See M.P.E.P. § 706.02(j).

Since the Office has not clearly set forth the basis for its rejection and has not met the criteria necessary to establish a *prima facie* case of obviousness, Applicants respectfully request the rejection be withdrawn and the claims allowed.

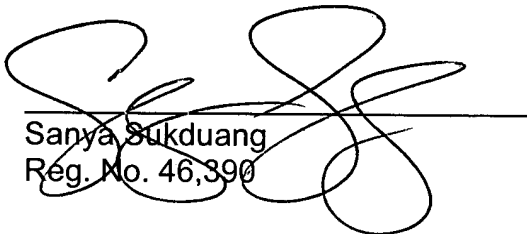
Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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Dated: September 8, 2003

By:

  
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